

## **REMARKS**

### **Status of the claims**

Claims 11-21 and 26 are pending in the present application. Claims 1 and 20 have been amended. No new matter has been added by way of the above amendments.

### **Statement of the substance of the interview**

Applicants would like to thank Exs. Lau and Jiang for their time and consideration with the interview of April 2, 2009. During the interview, the examiners and Applicants' representative discussed the number of steps in the claimed method versus the prior art. It was emphasized to the Examiner that whether claim 11 is interpreted as having two steps (i.e. a first step in which active substance and host material are reacted to give a first product and then a second step, in which the active substance/host molecule complex is further reacted with the agent for interaction) or five separate steps as listed a. through e. of claim 11, the claimed method is clearly different than the prior art, in which the active substance, host molecule and agent for interaction are all reacted at once. In response, the Examiner took the position that the recitation of "recovering" in stage "c" of claim 11 does not necessarily mean that the active substance/host molecule complex is first isolated or purified and then reacted with the agent for interaction.

Thus, the Examiner asserts that if the prior art reaction is performed some of the active substance and host molecule will react with each other and then react with the agent for interaction. This issue was unresolved during the interview, with Applicants' representative maintaining that the Examiner's interpretation of "recovering" is contrary to the common accepted meaning of "recovering" in chemistry, which is to separate the product of a reaction from the reactants.

The examiners further maintained that the Declaration evidence was not sufficient because only one complex was tested. Applicants' representative responded that the experiments compared the prior art example to the closest embodiment that would be encompassed by the claims. The Examiner agreed that the tested example was the closest to the prior art, but asserted that other complexes within the claim should be tested as well. The Examiner relied upon MPEP §716.02(d), which states that unexpected results must be commensurate in scope with the

claimed invention. However, Applicants' representative pointed out that this provision of the MPEP refers to the requirement that the Applicant compare the closest embodiment of the invention encompassed by the claims to the prior art, which the Examiner acknowledged was done in the Declaration.

### **Rejections under 35 U.S.C. §103**

Claims 11-21 and 26 remain rejected under 35 U.S.C. §103 as being obvious over Van Hees et al. 2002 and Van Hees 1999, in view of Junco et al.

In response to Applicants' arguments of October 14, 2008, the Examiner asserts that the recitation of stages in claim 11 is indicative of process steps and that the "order of the steps" would be obvious. The Examiner further asserts that the comparative showing in the specification is not commensurate in scope with the claims because the only example that was tested is with piroxacin with cyclodextrin. Applicants traverse this rejection and withdrawal thereof is respectfully requested.

As discussed during the interview, with the claimed method, two separate reactions are performed. In the first reaction, the active substance and host material are reacted to give a first product and then a second reaction is performed, in which the active substance/host molecule complex is further reacted with the agent for interaction. Thus, the claimed method is clearly different than that of the prior art, in which the active substance, host molecule and agent for interaction are all reacted at once. The Examiner takes the position that the recitation of "recovering" in stage "c" of claim 11 does not necessarily mean that the active substance/host molecule complex is first isolated or purified and then reacted with the agent for interaction. Applicants disagree with this interpretation of the meaning of "recovering". The common accepted meaning of "recovering" in chemistry, which meaning is also consistent with the experiments in the specification, is the separation of a product from reactants following a reaction.

However, to further clarify that there are separate reactions being conducted with the invention claim 11 has been amended to replace "stages" with "steps" and to recite that "successive steps" are performed.

Thus, with the present invention, there is a depressurization between steps (b) and (d) in order to recover the active substance/host molecule complex. Step (d) is, therefore, not carried out under pressure and the mixing of the active substance/host molecule molecular complex with the agent for interaction with the complex is not carried out in the presence of a pressurized fluid. The dense pressurized fluid is only present in step (b). The present invention has two separate reaction steps: a first reaction step, which is carried out under pressure by contacting a dense pressurized fluid with the mixture of the active substance and host molecule; and a second step, which is not carried out under pressure and which is performed in the absence of a dense pressurized fluid. In the second step, the agent for interaction with the active substance/host molecule molecular complex is simply added to the active substance/host molecule molecular complex. See, for example, Example 1 of the specification, which discloses that the mixture of the powder and ammoniacal solution after the “maturing stage” is placed in a ventilated oven at 60°C overnight and, thus, is not carried out in the presence of CO<sub>2</sub> under pressure. The claimed process is therefore clearly distinguished from and unobvious over the one-step process of Van Hees. et al.

The examiners further maintained that the Declaration evidence was not sufficient because only one complex was tested. However, as admitted by the Examiner, the experiments compared the prior art example to the closest embodiment that would be encompassed by the claims. The Examiner has acknowledged that the tested example was the closest to the prior art, but asserts that other complexes within the claim should be tested as well.

Applicants remind the Examiner that the comparative showing need not compare the claimed invention with all of the cited prior art, In re Fenn et al., 208 USPQ 470 (CCPA 1981), but only with the closest prior art. In re Holladay, 199 USPQ 516 (CCPA 1978); see also In re Merchant, 197 USPQ 785 (CCPA 1978); see also In re Wood et al., 202 USPQ 171 (CCPA 1979). In the case of chemical compounds, this means only the compound or compounds closest structurally thereto must be tested. In re Kuderna, 165 USPQ 575 (CCPA 1970). In fact, Applicant is permitted to test compounds which are even more closely related than those of the prior art. Ex parte Humber, 217 USPQ 265 (POBA 1981). Thus, the Examiner’s position with

Merchant, 197 USPQ 785 (CCPA 1978); see also In re Wood et al., 202 USPQ 171 (CCPA 1979). In the case of chemical compounds, this means only the compound or compounds closest structurally thereto must be tested. In re Kuderna, 165 USPQ 575 (CCPA 1970). In fact, Applicant is permitted to test compounds which are even more closely related than those of the prior art. Ex parte Humber, 217 USPQ 265 (POBA 1981). Thus, the Examiner's position with regard to sufficiency of the comparative testing is legally incorrect and the rejection must be withdrawn.

For the reasons discussed above, the present invention is neither disclosed nor suggested by the Van Hees et al. references. The secondary reference of Junco et al. fails to compensate for the deficiencies of the Van Hees et al. references. As such, withdrawal of the rejection is respectfully requested.

#### **Non-statutory obviousness-type double patenting rejection**

Claims 11-21 and 26 remain for non-statutory obviousness-type double patenting over claims 1-10 and 12 of co-pending application No. 10/554,058, in view of Van Hees et al. 2002. Applicants traverse this rejection and withdrawal thereof is respectfully requested. As discussed above, the present invention is drawn to a process that requires two separate reaction steps, the first of which is performed under pressure and the second of which is not, whereas the method of Van Hees et al. is performed as a single reaction under pressure. The two-reaction/two step method of the invention possesses unexpected advantages over the single-step reaction of Van Hees et al. In addition, it would not have been obvious to modify the method of Van Hees et al. to perform two separate reactions, which would require more time and effort. As such, the present invention of claims 11-21 and 26 is not obvious over the method of claims 1-10 and 12 of co-pending application No. 10/554,058. As such, withdrawal of the non-statutory obviousness-type double patenting is respectfully requested.


In view of the above amendments and Remarks, Applicants believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, Ph.D., Reg. No. 40,069 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: June 22, 2009

Respectfully submitted,

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